

IDS/6/57
J 2/19/02
TECH CENTER 1501/2901

RECEIVED

FEB 05 2002

Docket No. ORT-1501/2901

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Loretta ITRI and Peter BOWERS
Serial No.: 09/921,516 Art Unit: N/A
Filed: 1 August 2001 Examiner: N/A
For: **IMPROVED ANTI-VIRAL AND ANTI-TUMOR CHEMOTHERAPY
BY ADMINISTRATION OF ERYTHROPOIETIN**

I hereby certify that this correspondence is being deposited with the
United States Postal Service as first class mail in an envelope addressed
to: Commissioner for Patents, Washington, D.C. 20231 on

22 January 2002

(Date of Deposit)

John W. Wallen, III, Esq.

(Name of applicant, assignee, or Registered Representative)

(Signature)

22 January 2002

(Date of Signature)

Assistant Commissioner for Patents
Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

Applicant(s) reserve(s) the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

☒ In accordance with §1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified national application (other than a continued prosecution application under §1.53(d)), within three months of the date of entry into the national stage of the above identified application as set forth in §1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of a request for continued examination under §1.114, no additional fee is required.

☐ In accordance with §1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, therefore:

- ☐ Statement in Accordance with §1.97(e) (attached); or
- ☐ Please charge Deposit Account No. 10-0750/ORT-XXXX/JWW the fee of \$180.00 as set forth in §1.17(p).

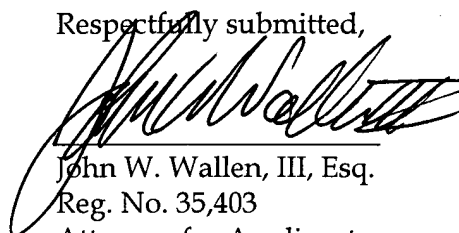
☐ In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, or an action that otherwise closes prosecution and that it is accompanied by one of:

- ☐ Statement in Accordance with §1.97(e) (attached); or
- ☐ Please charge Deposit Account No. 10-0750/ORT-XXXX/JWW the fee of \$180.00 as set forth in §1.17(p).
- ☐ In accordance with §1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311 but before the payment of the Issue Fee. Applicant(s) hereby petition(s) for consideration of this Information Disclosure Statement. Included are: Statement in Accordance with §1.97(e) as set forth below and the fee of \$180.00 as set forth in §1.17(p).
- ☒ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.
- ☐ Copies of references listed on the attached Form PTO-1449 are enclosed herewith EXCEPT THAT:
- ☐ In view of the voluminous nature of references [list as appropriate], and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.
- ☐ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.
- ☒ There are no listed references which are not in the English language.
- ☐ The relevance of those listed references which are not in the English language is as follows:
- ☒ Attached are copies of search report(s) from corresponding patent application(s), which are listed on the attached Submission Under MPEP 609 D.

☐ Attached are the following non-published pending patent applications which may be deemed relevant, which are listed on the attached Submission Under MPEP 609 D.

Please charge any deficiency or credit any overpayment to Deposit Account No. 10-0750/ORT-1462/JWW. This form is submitted in triplicate.

Respectfully submitted,



John W. Wallen, III, Esq.
Reg. No. 35,403
Attorney for Applicants

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, New Jersey 08933-7003
(858) 784-3239
DATE: 22 January 2002



SUBMISSION UNDER MPEP 609 D

Page 1 of 2

Application Number	09/921,516
Filing Date	1 August 2001
First Named Inventor	ITRI, Loretta
Group Art Unit	N/A
Examiner Name	N/A
Attorney Docket Number	ORT-1462

RECEIVED
FEB 05 2002
TECH CENTER 1600/2800

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No. ¹	Name of Patentee or Applicant of Cited Document	U.S. Patent Document		Pages, Columns, Lines, where relevant passages or relevant figures appear
			Number	Kind Code ² (if known)	

FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No. ¹	Name of Patentee or Applicant of Cited Document	Foreign Patent Document			Pages, Columns, Lines, where relevant passages or relevant figures appear	T ⁶
			Office ³	Number ⁴	Kind Code ⁵		

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITOL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
		Aviles et al., "Treatment of Refractory Low Grade Lymphoma with Chlorambucil Alternating with Interferon and Radiotherapy", <i>Cancer Biother.</i> (1995) 10(4):273-277.	
		Akpek et al., "Chemotherapy with Etoposide, Vincristine, Doxorubicin, Bolus Cyclophosphamide, and Oral Prednisone in patients with refractory cutaneous T-Cell Lymphoma" <i>Cancer</i> (1999) 86(7):11368-1376.	
		Bajorin et al., "Ifosfamide, Paclitaxel, and Cisplatin for Patients with Advanced Transitional Cell Carcinoma of the Urothelial Tract", <i>Cancer</i> (2000) 88(7):1671-1678.	
		Bourantas et al., "Combination Therapy with Recombinant Human Erythropoietin, Interferon-alpha-2b and Granulocyte-Macrophage Colony Stimulating Factor in Idiopathic Myelofibrosis", <i>Acta Haematol.</i> (1996) 96(2):79-82.	
		Cortes et al., "Result of Interferon-Alpha Therapy in Patients with Chronic Myelogenous Leukemia 60 Years of Age and Older", <i>Amer. J. Medicine</i> (1996) 100(4):452-455.	
		Hilbe et al., "Cladribine Treatment of a Patient with Hairy Cell Leukemia and Concomitant Multiple Sclerosis", <i>Acta Haematol.</i> (1999) 102(2):99-100.	
		Hinotsu et al., "Intravesical Chemotherapy for Maximum Prophylaxis of New Early Phase Superficial Bladder Carcinoma Treated by Transurethral Resection: A Combined Analysis of Trials by the Japanese Urological Cancer Research Group using Smoothed Hazard Function", <i>Cancer</i> (1999) 86(9):1818-1826.	
		McPherson et al., "Suppression of Hepatitis C Virus in Human Immunodeficiency Virus Iron-Loading Anemia (HCV-HIV-ILA) Patients with HAART and Recombinant Human Erythropoietin (r-HuEPO)", (2000) 96(11, Part 2):7B.	
		Naglieri et al., "Standard Interleukin-2 (IL-2) and Interferon-alpha Immuno-therapy Versus an IL-2 and 4-Epirubicin Immuno-Chemotherapeutic Association in Metastatic Renal Cell Carcinoma", <i>Anticancer Res.</i> (1998) 3B:2021-2026.	

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

RECEIVED

FEB 05 2002

TECH CENTER 1600/2900



SUBMISSION UNDER MPEP 609 D Page 1 of 2	Application Number	09/921,516
	First Named Inventor	ITRI, Loretta
	Attorney Docket Number	ORT-1462

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITOL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
		<u>Peuckmann</u> et al., "Potential Novel Uses of Thalidomide Focus on Palliative Care", <i>Drugs</i> (2000) 60(2):273-292.	
		<u>Pronzato</u> et al., "Biochemical Modulation of 5-fluorouracil with Methotrexate in Advanced Colorectal Cancer Patients Pretreated with Adjuvant 5-fluorouracil and Leucovorin", <i>Anticancer Res.</i> (1995) 15(6B):2679-2682.	
		<u>Tetreault</u> et al., "Treatment of Hairy Cell Leukemia-variant with Cladribine", <i>Leukemia and Lymphoma</i> (1999) 35(3-4):347-354.	
		E. L. Trimble, "Innovative Therapies for Advanced Ovarian Cancer", <i>Sem. Oncology</i> (2000) 27(3, Supp. 7):24-30.	

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--